STATE OF MICHIGAN

DEPARTMENT OF LABOR & ECONOMIC GROWTH

OFFICE OF FINANCIAL AND INSURANCE SERVICES

Before the Commissioner of Financial and Insurance Services

In the matter of

XXXXX
Petitioner

v **File No. 120615-001**

Blue Cross Blue Shield of Michigan
Respondent

Issued and entered
this 20th day of October 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On April 15, 2011, XXXXX (Petitioner) filed a request for external review with the Commissioner of Financial and Insurance Services under the Patient's Right to Independent Review Act (PRIRA), MCL 550.1901 *et seq*. The Commissioner reviewed the material submitted and accepted the request on April 22, 2011.

The Commissioner immediately notified Blue Cross Blue Shield of Michigan (BCBSM) of the external review and requested the information it used to make its final adverse determination. The Commissioner received BCBSM's response on May 2, 2011.

Because the case involves medical issues the Commissioner assigned it to an independent review organization which provided its analysis and recommendations to the Commissioner on May 6, 2011.

II. FACTUAL BACKGROUND

The Petitioner is enrolled for health coverage through a group underwritten by BCBSM. Her benefits are defined in the *Community Blue Group Benefits Certificate* (the certificate).

On November 5, 2009, December 2, 2009, and January 5, 2010, the Petitioner received injections of Traumeel. BCBSM denied coverage for the injections, stating they are not the standard of care for treatment of the Petitioner's injuries and therefore were not medically necessary.

The Petitioner appealed the denial through BCBSM's internal grievance process. After a managerial-level conference on January 21, 2011, BCBSM did not change its decision and issued a final adverse determination dated February 14, 2011.

III. ISSUE

Did BCBSM properly deny coverage for the Petitioner's Traumeel injections?

IV. ANALYSIS

Petitioner's Argument

The Petitioner suffers from pain caused by injuries received in a motor vehicle accident. On November 5, 2009, she began receiving injections of Traumeel. Her physician's office notes from that day explain the treatment:

> [The Petitioner] presents today to undergo her first series of traditional trigger point and tendon insertion injections for her motor vehicle accident related injuries, specifically posttraumatic regional myofascitis (cervical/ periscapular) and enthesopathy involving the upper extremities. Trigger point injections are part of the usual and customary standard of care in the management of myofascitis as well as enthesitis/enthesopathy. Typically, a patient may need anywhere from one to four series of injections to facilitate muscle recovery, increased blood flow and oxygenation, and improved muscle metabolism.

The Petitioner states that the injections have been effective in the relief of her symptoms. She disputes BCBSM's contention that the treatments are not medically necessary. The Petitioner believes that BCBSM is required to provide coverage for the injection therapy.

BCBSM's Argument

After receiving the final adverse determination of February 14, 2011, the Petitioner submitted additional information to BCBSM. Responding to the Petitioner in a letter dated April 4, 2011, BCBSM repeated and elaborated on its reasons for denying coverage:

> Our medical consultants reviewed the new documentation you recently submitted as well as the prior information. Based on that review, our

> denial of payment must be maintained. It is our consultants' opinion based on the new documentation that although this may be FDA approved, it is not approved by BCBSM because it is not considered medically necessary and is still not considered to be the standard of care. This is a homeopathic treatment and has not been supported and validated by the medical literature. It is therefore, considered experimental and the services are not payable.

Commissioner's Review

The certificate, in "Section 7: The Language of Health Care" (p. 7.14), states: "A service must be medically necessary to be covered." The certificate then goes on to define "Medical necessity for payment of professional provider services" as follows:

> Health care services that a professional provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease and its symptoms, and that are:
>
> – In accordance with generally accepted standards of medical practice;
>
> – Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the member's illness, injury or disease and
>
> – Not primarily for the convenience of the member, professional provider, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that member's illness, injury or disease.
>
> **NOTE:** "Generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician or provider society recommendations and the views of physicians or providers practicing in relevant clinical areas and any other relevant factors.

The question of whether the Petitioner's Traumeel injections were medically necessary was presented to an independent review organization (IRO) for analysis, as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician who is in active practice, and who is certified by the National Board of Osteopathic Medical Examiners and the American Board of Physical Medicine and Rehabilitation. The IRO report stated in part:

It is the determination of this reviewer that the injection therapy (Traumeel) rendered on dates of service November 5, 2009; December 2, 2009 and January 5, 2010 was not medically necessary for the treatment of the [Petitioner's] condition.

Clinical Rationale for the Decision:

Traumeel injection solution is a homeopathic combination remedy of an anti-inflammatory, anti-edematous, anti-exudative combination formulation of 12 botanical substances and 1 mineral. It appears to be indicated for the treatment of symptoms associated with inflammatory, exudative, and degenerative processes due to acute trauma, repetitive or overuse injuries and minor aches and pains associate[d] with such conditions. The use of Traumeel is the subject of several clinical trials. Several clinical trials have been completed while others are in the recruiting phase. Thus, the use of Traumeel is currently experimental/ investigational as it has not been thoroughly evaluated and its use is in not in keeping with the expected standards of care and is not considered medically necessary.

It is not clear from the medical records submitted for review why the [Petitioner] did not undergo trigger point injections to decrease soreness; trigger point injections can be done with dry needling alone or with saline and lidocaine. These therapies are considered to be the standard of care for this patient's condition. It does not appear the enrollee has contraindications to either.

The standard definition of trigger point injections (TPIs) is injecting fluid directly into the trigger point. . . . Other needling techniques include injection of fluid over the trigger point into the skin or subcutaneous tissue, direct dry needling, or indirect dry needling. The injection of a local anesthetic can reduce the pain of a trigger point. TPIs with an anesthetic are recommended for non-resolving trigger points. The addition of a local anesthetic can reduce the pain of injection. The addition of a corticosteroid is not generally recommended and there is moderate evidence that TPIs with corticosteroids do not produce significantly different results from placebo injections using short-term self reports. Current evidence does not support the use of Botulinum toxin in trigger point injections for myofascial pain.

* * *

Thus, the use of Traumeel is currently experimental/investigational as it has not been thoroughly evaluated and its use is in not in keeping with the expected standards of care and is not considered medically necessary.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner finds that the Traumeel injections were not medically necessary for the Petitioner's condition and therefore are not a covered benefit under the certificate.

V. ORDER

Respondent Blue Cross Blue Shield of Michigan's February 14, 2011, final adverse determination is upheld. BCBSM is not required to cover the Petitioner's Traumeel injections.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of the Office of Financial and Insurance Services, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.